Irish Standard
I.S. EN ISO 19001:2013

In vitro diagnostic medical devices - Information supplied by the manufacturer with in vitro diagnostic reagents for staining in biology (ISO 19001:2013)

I.S. EN ISO 19001:2013

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English Version

In vitro diagnostic medical devices - Information supplied by the manufacturer with in vitro diagnostic reagents for staining in biology (ISO 19001:2013)

Dispositifs médicaux de diagnostic in vitro - Informations fournies par le fabricant avec les réactifs de coloration de diagnostic in vitro utilisés en biologie (ISO 19001:2013)

In-vitro-Diagnostika - Bereitstellung von Informationen durch den Hersteller von in-vitro-diagnostischen Reagenzien für biologische Färbungen (ISO 19001:2013)

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Foreword

This document (EN ISO 19001:2013) has been prepared by Technical Committee ISO/TC 212 "Clinical laboratory testing and in vitro diagnostic test systems" in collaboration with Technical Committee CEN/TC 140 “In vitro diagnostic medical devices” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2013, and conflicting national standards shall be withdrawn at the latest by March 2016.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

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The text of ISO 19001:2013 has been approved by CEN as EN ISO 19001:2013 without any modification.

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I.S. EN ISO 19001:2013

INTERNATIONAL STANDARD

ISO 19001

Second edition
2013-03-15

In vitro diagnostic medical devices — Information supplied by the manufacturer with in vitro diagnostic reagents for staining in biology

Dispositifs médicaux de diagnostic in vitro — Informations fournies par le fabricant avec les réactifs de coloration de diagnostic in vitro utilisés en biologie

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 19001 was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

This second edition cancels and replaces the first edition (ISO 19001:2002), which has been technically revised.

Introduction

This International Standard relates to ISO 18113-1 and ISO 18113-2, which can be used in conjunction with it.

The use of reagents required for staining in biology as well as the specific examples of information supplied by the manufacturer for two staining procedures as provided in Annex A are based on a European consensus; they constitute the scientific justification for the requirements listed in Clause 4. This information is intended to assist manufacturers, suppliers and vendors of dyes, stains, chromogenic reagents and other reagents used for staining in biology in complying with the required specific product data.

In vitro diagnostic medical devices — Information supplied by the manufacturer with in vitro diagnostic reagents for staining in biology

1 Scope

This International Standard specifies requirements for information supplied by the manufacturer with reagents used in staining in biology. It applies to producers, suppliers and vendors of dyes, stains, chromogenic reagents and other reagents used for staining in histology and cytology including bacteriology, haematology, histochemistry, as performed in medical laboratories, both routine and research bacteriology. The requirements for information supplied by the manufacturer specified in this International Standard are a prerequisite for achieving comparable and reproducible results in all fields of staining in biology.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 80000-1, *Quantities and units — Part 1: General*

ISO 80000-9, *Quantities and units — Part 9: Physical chemistry and molecular physics*

ISO 18113-1, *In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements*

ISO 18113-2, *In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 2: In vitro diagnostic reagents for professional use*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
antibody
specific immunoglobulin formed by B-lymphocytes in response to exposure to an immunogenic substance and able to bind to this

Note 1 to entry: The molecule of an immunogenic substance contains one or more parts with a characteristic chemical configuration, an epitope.

3.2
blocking reagent
reagent that is used to reduce the inherent background of a sample before staining

3.3
chromogenic reagent
reagent that reacts with certain chemical groups present or induced in cells and tissues with the formation of a coloured compound in situ

EXAMPLE Diazonium salt, Schiff's reagent.

3.4
dye
coloured organic compound that, when dissolved in a suitable solvent, can impart colour to a material

3.5
fluorochrome
reagent that emits visible light when irradiated with excitation light of a shorter wavelength

Note 1 to entry: Any of various fluorescent substances used in biological staining to produce fluorescence in a sample.

3.6
in vitro diagnostic reagent
IVD reagent
chemical, biological or immunological component, solution or preparation intended by the manufacturer to be used as an IVD medical device

[ISO 18113-1]

3.7
information supplied by the manufacturer
labelling
written, printed or graphic matter

— affixed to an IVD medical device or any of its containers or wrappers or

— provided for use with an IVD medical device,

related to identification, technical description, and use of the IVD medical device, but excluding shipping documents

EXAMPLE Labels, instructions for use.

Note 1 to entry: Catalogues are not considered labelling of IVD medical devices.

[ISO 18113-1]

3.8
label
printed, written or graphic information placed on a medical device or its container

Note 1 to entry: A label permanently affixed to an IVD instrument is considered marking.

[ISO 18113-1]

3.9
lectin
protein of non-immunogenic origin with two or more binding sites that recognize and bind to specific saccharide residues

3.10
monoclonal antibody
antibody capable of reacting specifically with a single epitope of a certain immunogenic substance

3.11
polyclonal antibody
mixture of immunoglobulin molecules, secreted against a specific immunogenic substance, each recognizing a different epitope

3.12
staining
impartment of colour to a material by means of reaction with a stain or chromogenic reagent

3.13
stain
solution of one or more dyes at defined concentrations in a defined solvent used for staining

Note 1 to entry: The stain can be prepared by directly dissolving the dye in the solvent or by dilution of a stock solution with suitable agents.

3.14
stock solution of stain
stable defined solution of one or more dyes at a higher concentration than that used for staining

Note 1 to entry: Stability refers to constant properties of the dye even in the presence of other dyes.

3.15
nucleic acid probe
single- or double-stranded oligonucleotide or polynucleotide of defined length complementary to specific sequences of nucleotides in nucleic acids

4 Requirements for information supplied by the manufacturer

4.1 General requirements

4.1.1 Chain of suppliers

When a manufacturer uses materials supplied by a producer, the manufacturer has an obligation of assuring that the producer meets the quality systems described in ISO 9001 and ISO 13485.

4.1.2 Warning and precautions

The manufacturer of reagents used for staining in biology shall provide information regarding warning and precautions in accordance with ISO 18113-1 and ISO 18113-2.

4.1.3 Format of Information supplied by the manufacturer

The format of the information supplied by the manufacturer with reagents used for staining in biology shall be in accordance with ISO 80000-1 and ISO 80000-9. Furthermore, where relevant, the requirements as specified in 4.1.4, 4.1.5 and 4.1.6 shall be met for the various reagents used for staining in biology.

4.1.4 Information supplied by the manufacturer with reagents used for staining in biology

Information supplied by the manufacturer with reagents used for staining in biology shall be in accordance with ISO 80000-1 and ISO 80000-9. Information shall be provided regarding warning and precautions. ISO 18113-1 and ISO 18113-2 regarding warnings and precautions apply. Furthermore, where relevant, the requirements as specified in 4.1.2, 4.1.3 and 4.1.4 shall be met for the various reagents used for staining in biology.

4.1.5 Product name

The product name shall, where relevant, include CAS-registry number [7] and Colour Index name and number.[23]

NOTE 1 CAS-registry numbers are the Chemical Abstracts Service registry numbers. These are unique numerical code numbers assigned to chemical substances indexed by Chemical Abstracts.

NOTE 2 The Colour Index gives a 5-digit number, the C.I. number and a specially constructed name to most dyes.